臨床藥學研究及健保資料庫的運用

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大綱

- 國內臨床藥學研究概況
- 運用健保資料庫於臨床藥學研究之經驗

臺灣臨床藥學研究之啟動

- 各大醫學中心推動臨床藥學服務
  -1980年代中、後期
- 成大醫學院臨床藥學研究所-1993年創立
- 台大藥學研究所醫院藥學組-1993年始招生
- 台大臨床藥學研究所-2000年成立
- 之後，其他藥學院、系陸續推出臨床藥學碩士生招收，進行相關研究

國家圖書館
國內期刊論文索引系統

檢索用詞：臨床藥學

結果：277篇

文章出處：

台灣臨床藥學雜誌—255篇

醫院藥學—8篇

藥學雜誌—7篇

台北市藥師公會會刊—2篇

國防藥學—2篇

醫學教育、北市衛生月刊、臨床醫學各1篇

國家圖書館
期刊論文索引系統

檢索用詞：臨床藥學

結果：277篇

論文屬性：

- Case Report
- Drug Utilization Evaluation
- Adverse Drug Reactions / Medication Errors
- System and QA of Pharmacy Practice
- Prescription Pattern Analysis
- Bioequivalence Studies of Generic Drug
- Therapeutic Drug Monitoring
- Others

國家圖書館
全國博碩士論文資訊網

檢索用詞：臨床藥學&健保資料庫

結果：22筆

檢索用詞：用藥型態分析&健保資料庫

結果：7筆

檢索用詞：藥物不良反應&健保資料庫

結果：5筆

檢索用詞：用藥趨勢&健保資料庫

結果：4筆

總共：28筆

MedLine Searching

Searching keyword: National Health Insurance Database

Paper found: 442 articles

Limited to Humans: 428 articles

Limited to Taiwan: 105 articles

MedLine Searching

Distribution of these 105 Taiwan articles by publishing year:

2008 – 24	2004 – 14
2007 – 22	2003 – 8
2006 – 22	2002 – 6
2005 – 9	

Among them, 30 (28.6%) are drug related studies, 53 (50.5%) are diseases oriented, the rest are more or less related to the discussion on medical resource allocations of NHI program.

臨床研究的啟動

臨床觀察，提出疑問

文獻資料搜尋

計畫規劃（目的，研究設計等）

計畫執行

數據分析，報告

依研究方法分類

- 前瞻性臨床研究
  - 臨床試驗
  - 臨床病例收集—療效、不良反應
  - 問卷調查
  - 其他
- 回溯性臨床研究
  - 病歷調閱
  - 處方型態分析
  - 藥物流行病學研究
  - 其他

- 藥物使用評估之臨床藥學研究，開始以醫院之電腦就醫記錄配合病歷回顧之回溯性研究為主，例如：氣喘用藥型態分析、降血脂藥物分析、Carbamazepine使用處方型態分析等
- 前瞻性研究則如：Methylphenidate MR劑型之臨床試驗、結核病藥物肝毒性之前瞻性研究、等

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Determinants of Adherence to Methylphenidate and the Impact of Poor Adherence on Maternal and Family Measures

Susan S.F. Gau, M.D., Ph.D.,[1,2] Hsin-Yi Shen, M.S.,[3] Miao-Churn Chou, M.D.,[4] Ching-Shu Tang, M.D.,[4] Yen-Nan Chiu, M.D.,[1] and Churn-Shiouh Gau, Ph.D.[3]

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Pp. 441–455

An Open-Label, Randomized, Active-Controlled Equivalent Trial of Osmotic Release Oral System Methylphenidate in Children with Attention-Deficit/Hyperactivity Disorder in Taiwan

Susan Shur-Fen Gau, M.D., Ph.D.,[1] Hsin-Yi Shen, M.S.,[2] Wei-Tusen Soong, M.D.,[1] and Churn-Shiouh Gau, Ph.D.[2,3]

- 1998年執行藥物不良反應自動通報系統，開始涉獵藥物流行病學研究，初期如：感染科病房藥物不良反應，結核病藥物肝毒性之前瞻性研究、等
- 2004年開始參與衛生署藥政處、國衛院合作辦理，探討以健保申報資料庫研究藥物的使用合理性、藥物不良反應等相關議題，以作為藥政管理政策之實證之可行性的討論會議

關於Cisapride 開方合理性之研究

PHARMACOEPIDEMIOLOGY AND DRUG SAFETY 2007; **16**: 86–95
Published online 28 September 2006 in Wiley InterScience (www.interscience.wiley.com) **DOI**: 10.1002/pds.1324

ORIGINAL REPORT

Usage of the claim database of national health insurance programme for analysis of cisapride-erythromycin co-medication in Taiwan†

Churn-Shiouh Gau PhD[1], I-Shou Chang PhD[2], Fe-Lin Lin Wu PhD[1], Hui-Tzu Yu MSc[3], Yu-Wen Huang MSc[4], Cheng-Liang Chi MSc[3], Su-Yu Chien MSc[5], Keh-Ming Lin MD, PhD[6], Ming-Ying Liu MSc[2] and Hui-Po Wang PhD[7]*

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Two subset databases of NHIRD, i.e., Outpatient Sampling Database (OSD) and Longitudinal Health Insurance Database 2000 (LHID 2000), in the study.

The Outpatient Sampling Database (OSD) consists of ambulatory care expenditures and the associated details of care orders by ambulatory visits. A systematic sampling method was applied to randomly sample a representative database of ambulatory care expenditures by visits from the entire database. The sampling rate is 0.2% and the size of the subset for each month is determined by the ratio of the amount of data in each month to that of the entire year. The OSD of each year is then obtained by combining the subsets for the 12 months of the year. We employed various methods to validate the representative of the OSD, which would demonstrate the validity of the OSD. For example, there was no significant difference in the distribution of patient visits in different specialties of clinics between the OSD and the original NHIRD (Chi square statistics $(\chi^2) = 44.62$, degree of freedom $(df) = 46$, $p = 0.530$).

The LHID2000 contains all the original claim data of 200 000 individuals randomly sampled from the Registry for Beneficiaries 2000 of the NHIRD, which maintains the registration data of any individual who was once a beneficiary of NHI programme during the period of 1996–2000. There are approximately 23 720 000 individuals in this registry. All the registration and claim data of these 200 000 individuals collected by the NHI programme constitute the LHID2000. The database has been used for related studies.[25] Again, we employed several methods to validate the representative of the LHID2000 before we conducted our analysis. For example, there was no significant difference in the gender ($\chi^2 = 1.74$, $df = 1$, $p = 0.187$) distribution between the patients in the LHID2000 and the original NHIRD.

Table 1. Estimated number of cisapride prescriptions per 100 thousand beneficiaries made by different categories of health institute in years 1999 to 2002. Data were retrieved from the OSD database

Health Institute*	Year			
	1999	2000	2001	2002
Medical centres	2217	1249	846	828
Regional hospitals	3176	1699	1309	1462
Local hospitals	3369	1427	1050	933
Clinics	9845	7260	6705	6161
Total	18 607	11 634	9910	9384

*The health institutes in Taiwan are categorized as medical centres, regional hospitals, and local hospitals, according to the accreditation programme held by Taiwan Joint Commission on Hospital Accreditation (TJCHA),[23] based on their number of beds, facilities, quantity and quality of medical personnel, quality of services, educational programme etc. However, clinics in Taiwan do not have any accreditation so far.

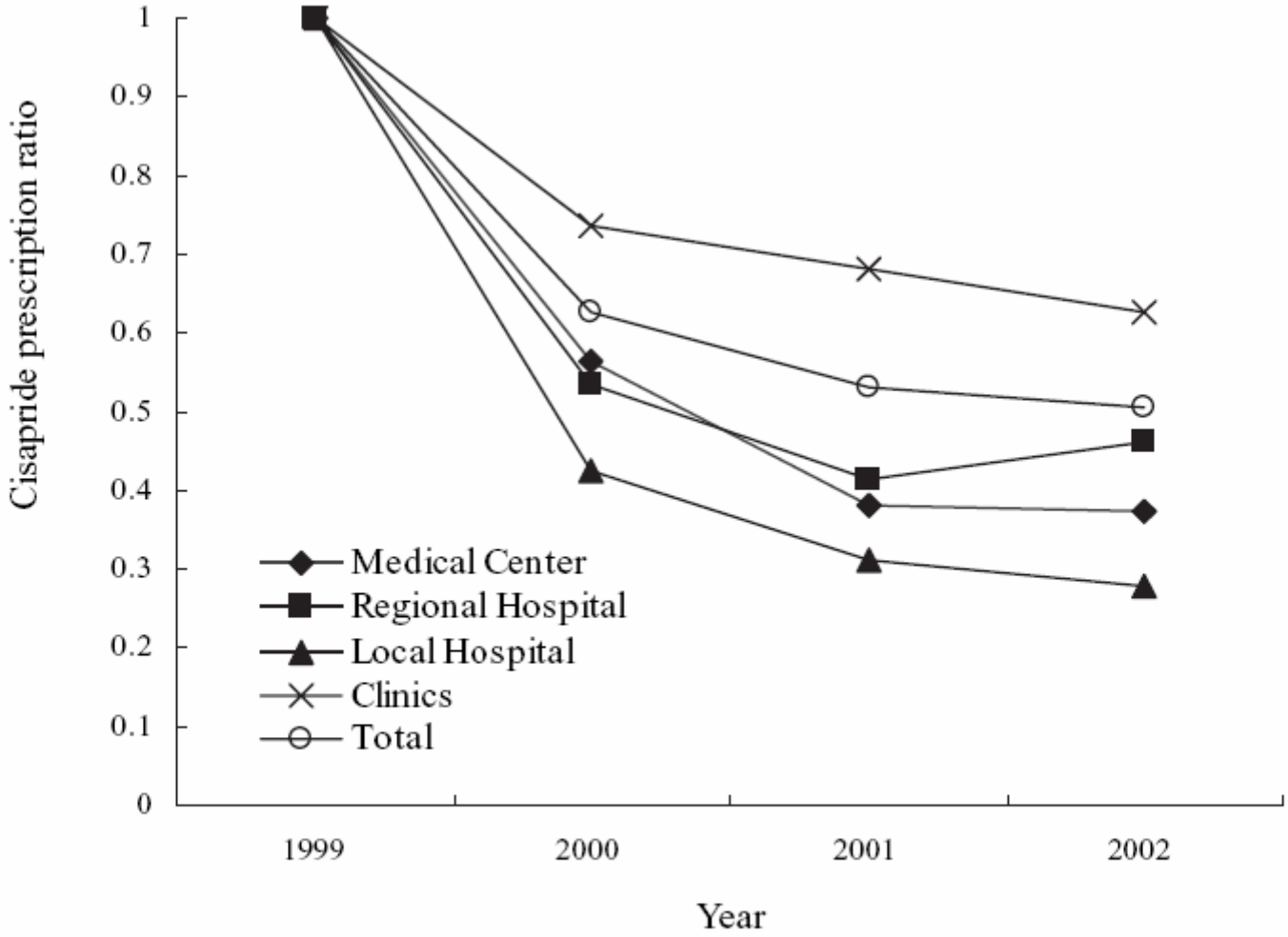


Figure 2. Ratio of cisapride prescription in 2000—2002 with respect to that of year 1999 for different categories of health institute, data from Table 1

Table 2. Demographic data of total cisapride users and those who exposed to cisapride-erythromycin co-medications. Data retrieved from the LHID2000 database

	Cisapride users of different age group, patient number (%)					
	0~12 years	13~18 years	19~45 years	46~65 years	>65 years	All ages
All cisapride users[a]						
Total	5175 (50.5)	364 (3.6)	2103 (20.5)	1461 (14.2)	1155 (11.3)	10258 (100)
Female	2442 (47.2)	212 (58.2)	1304 (63.0)	813 (55.7)	556 (48.2)	5327 (51.9)
Male	2728 (52.8)	152 (41.8)	765 (37.0)	647 (44.3)	598 (51.8)	4890 (47.7)
Missing	5	0	34	1	1	41
Cisapride users who exposed to cisapride-erythromycin co-medications[b]						
Total	362 (78.0)	7 (1.5)	40 (8.6)	27 (5.8)	28 (6.0)	464 (100.0)
Female	162 (44.7)	5 (71.4)	24 (60.0)	15 (55.6)	14 (50.0)	220 (47.4)
Male	200 (55.3)	2 (28.6)	16 (40.0)	12 (44.4)	14 (50.0)	244 (52.6)
Incidence rate	7.00%	1.92%	1.90%	1.85%	2.42%	4.52%

[a]Gender difference across the 5 age groups ($\chi 2 = 168.15$, df = 4, $p < 0.0001$).
[b]No gender difference across the 5 age groups ($\chi 2 = 5.98$, df = 4, $p = 0.200$).

Table 3. Cisapride prescriptions and cisapride-erythromycin co-medications in each category of health institute. Data were retrieved from the LHID2000 database

Health institute	Number of cisapride prescriptions (%)	Cisapride-erythromycin co-medication	
		Number	Percentage (95%CI)
Medical centres	2276 (10.3%)	55	2.4(2.0, 2.9)
Regional hospitals	3031 (13.7%)	75	2.5(2.0, 2.9)
Local hospitals	2829 (12.8%)	59	2.1 (1.7, 2.5)
Clinics	14039 (63.3%)	496	3.5 (3.0, 4.1)
Total	22175 (100%)	685	3.1 (2.6, 3.6)

A total of 464 individuals experienced 685 episodes of cisapride-erythromycin co-medication prescribed by 295 physicians.

Table 4. Number of cisapride prescribers and those who responsible for the co-medication of cisapride and erythromycin in different categories of health institute, based on the LHID2000 database

Health institute	Number (%) of cisapride prescribers	Cisapride prescribers responsible for co-medication	
		Number	Percentage (95%CI)
Medical center	619 (14.6%)	33	5.3 (4.7, 6.0)
Regional hospital	780 (18.4%)	42	5.4 (4.7, 6.1)
Local hospital	759 (17.9%)	28	3.7 (3.1, 4.2)
Clinic	2,082 (49.1%)	192	9.2 (8.4, 10.1)
Total	4,240 (100%)	295	7.0 (6.2, 7.7)

The results revealed a prevalence of 4.5% concomitant use, with higher prevalence in clinics (9.2%) than in other medical institutes (3.7-5.4%).

Table 5. Results of source analysis of cisapride and erythromycin prescriptions for the co-medication episodes.

Health institute	From same doctor			From different doctors	
	From different health institutes	From same health institute		From different health institutes	From same health institute
Medical centres	0	11		20	24
Regional hospitals	0	22		21	32
Local hospitals	0	22		15	22
Clinics	1	366		67	62
Category subtotal	1	421		123	140
Total			685		

Among the co-medication episodes, 81.9% and 61.2% were prescribed from the same health institutes and by the same physicians, respectively.

Table 6. Distribution of cisapride prescriptions with a cisapride dosage higher than 0.8 mg/kg/day in year 2000 based on LHID2000

Health institute	cisapride dose >0.8 mg/kg/day	
	All cisapride prescriptions	Co-medication cases
Medical centers	48 (5.1%)	0 (0%)
Regional hospitals	83 (8.9%)	1 (9.1%)
Local hospitals	95 (10.1%)	1 (9.1%)
Clinics	710 (75.9%)	9 (81.8%)
Total	936 (100%)	11 (100%)

No medical record of cardiac arrhythmias was found among these patients in 2001 and 2002, probably due to the fact that:

- 78.9% of the 464 individuals were under age 16,
- 84.0% had short exposure duration (1-4 days),
- 98.0% of the episodes were prescribed with a cisapride dose of less than 0.8 mg/kg/day.

Physicians in clinics tended to have a higher incidence of such concomitant prescribing behavior.

Limitations

Several methodological limitations should be considered when interpreting the findings in this study. First, the data were retrieved from the medical and pharmacy claim database of the NHI programme. Due to ethical considerations, there was no way to gain access to the medical records of each patient. The findings of this study would be more reliable if they could be validated by the medical records of the patients in this study. Second, the number of diagnoses in the claim data for each medical visit is limited by the BNHI, where a maximum of only three diagnoses for the ambulatory care and five for each inpatient admission were allowed. Combining with this limitation and the lack of medical records, exists the potential hazard of drug co-medication cardiac-related adverse events to be overlooked. Third, comparisons in the reduction of cisapride prescriptions were based on the assumption that the distribution of medical visits in different medical care institutes for ambulatory care were the same during years 1999–2002. This calculation may not be precise. However, the measurement error should be acceptable. Fourth, the dosage calculation may not exactly reflect the true individual dosage situation since patient compliance data was not assessable and patient body weight data was usually not updated in the claim data.

Pharmacoepidemiology continuing

衛生署科技計畫：
全民健保精神疾病住院病患歸人檔縱貫性藥物流行病學研究 -以精神分裂病和躁鬱病為例

資料庫：全民健保精神疾病住院病患歸人檔2002 (Psychiatric Inpatient Medical Claim Dataset 2002，PIMC 2002)

全民健保精神疾病住院病患歸人檔(PIMC 2002)建立之工作團隊成員：

張景瑞[1]　邱淑怡[2]　張新儀[2]　丘政民[2]
高淑芬[3]　陳為堅[4]　張憶壽[2]
[1]國泰綜合醫院精神科；[2]國家衛生研究院；[3]國立台灣大學醫學院精神科；[4]國立台灣大學流行病學研究所

PIMC 發展大事紀

- 2002.11.17: Professor PB Mortensen 來台演講並與 NHRI 團隊討論後續計畫
- 2002.12- 2003.10

  NHRI team 經過 11 次會議，完成1996至2001年間至少曾住過一次精神科病房的精神疾病病患的所有就醫紀錄，所建立之歸人檔
- 2003.10.3

  最後修訂，以全民健保精神疾病住院病患歸人檔(PIMC 2002) 命名之
- 2004.3.26: 資料檔公開發行

PIMC-樣本選取

於1996年至2001年之「全民健保住院醫療費用清單明細檔」(Inpatient expenditures by admissions，即DD檔) 依下列條件進行篩選：

1. 就醫科別為精神科(代碼13)
2. 出院診斷中任一診斷符合下列條件之一：

   ICD-9-CM 診斷碼前三碼 290 至 319 或

   A-code A210至A219
3. 同時符合條件 1 和條件 2 者，擷取其已轉碼之ID，經歸人後，共得到 91,104 個ID

PIMC-資料擷取

依此91,104個ID，在1996年至2002年之『全民健保研究資料庫』，擷取其所有就醫資料，包括下述各檔：

(i)「門診處方及治療明細檔」(Ambulatory care expenditures by visits，簡稱CD檔)、

(ii)「門診處方醫令明細檔」(Details of ambulatory care orders，簡稱OO檔)、

(iii)「住院醫療費用清單明細檔」(Inpatient expenditures by admissions，簡稱DD檔)、

(iv)「住院醫療費用醫令清單明細檔」(Details of inpatient orders，簡稱DO檔)

(v)「承保資料檔」(Registry for beneficiaries，簡稱 ID檔)

資料量總計約 10.32GB。

Basic features of PIMC cohort (n=91,104)

- Gender: M 51,787 (57.6%)
  F 38,078 (42.4%)
- Mean age: 42.8 (16.7)
- Diagnosis

schizophrenia(295) N=49,425 (54.3%)
mood disorders(296) N=25,355 (27.8%)
other diagnoses N=16,324 (17.9%)

Representativeness of PIMC dataset (2002)

	schizophrenia	mood disorders
PIMC	49,425	25,355
Total IPD and OPD cases by DOH statistics	93,234	151,960
% of total cases	53%	17.2%

http://www.doh.gov.tw/statistic/data/全民健康保險統計年報/91醫療統計年報/9113.xls

Medical Claims of PIMC cohort

	1996	1997	1998	1999	2000	2001	ALL
Inpa-tient	22,326	25,423	27,715	31,780	35,897	41,786	91,104
OPD	225,557	254,010	287,170	324,956	366,811	422,215	933,277

Psychiatric hospitalizations of PIMC cohort (n= 91,104)

- Only acute ward n= 29,404 (32.3%)
- Only chronic ward n= 8,348 (9.2%)
- Acute and chronic ward n= 53,352 (58.6%)

Population of long-stay inpatients (chronic ward >181 days/year)

	1996	1997	1998	1999	2000	2001
Claims chronic wards	9,583	10,100	10,708	13,369	15,093	17,294
long stay	6,177	6,186	6,738	7,765	8,978	10,044
% of chronic wards	64.5%	61.3%	62.9%	58.1%	59.5%	58.1%
% of PIMC	6.8%	6.8%	7.4%	8.5%	9.9%	11%

Validation

(I)與衛生署統計年報住院人數作比較

	1998	1999	2000	2001
PIMC	27,715	31,780	35,897	41,786
DOH	27,321	31,396	30,204	41,301

(II)與20萬人承保抽樣歸人檔 (住院) 作比較

	1996	1997	1998	1999	2000	2001	ALL
PIMC	22,326	25,423	27,715	31,780	35,897	41,786	91,104
LHID	171	206	239	265	282	362	747

Limitations of PIMC Dataset

- 僅能代表部分嚴重精神病患，主要是精神分裂症病人
- 日間病房與慢性病房區分不易
- Outcome 資料不足: 缺乏 financial and mortality data
- Confidentiality: Scrambled ID 無法與原始病歷核對，只能間接核對資料的正確性

Advantages of PIMC as a tool of pharmacoepidemiology by Strom criteria

1. Relative size: excellent, nation-wide
2. Population based: excellent,

   NHI cover > 98% of population in Taiwan.
3. Representativeness: PIMC-schizophrenia constitute 53% of total cases, PIMC-mood disorders only 17%.
4. Inpatient exposure data: moderate,

   lacking of prescription duration data.

Advantages of PIMC as a tool of pharmacoepidemiology by Strom criteria

5. (Outpatient) Diagnosis data: good, but not covering never-admitted OPD cases
6. Cohort study possible: yes
7. Case-control study possible: yes
8. Validity of exposure data: unknown
9. Validity of outcome data: weak, linkage needed.

Advantages of PIMC as a tool of pharmacoepidemiology by Strom criteria

10. Control of confounding: weak, scrambled ID made record checking difficult.
11. Loss to follow up: unknown, but traceable.
12. Relative cost: excellent.
13. Relative speed: good.
14. Dates of available data: near the beginning of NHI (1995)

PIMC-總檔整理(1)

步驟一：性別、ID欄不合理者

	刪除ID數	總ID數	總筆數
1.將1996-2001年的dd檔合併	---	91,104	893,385
2.刪除id_sex欄位為"U"的外國人及欄位"空白"者	1,239 (1.4%)	89,865	875,050
3.刪除ID不完整者	1	89,864	875,048

PIMC-總檔整理(2)

步驟二：檢視每個ID之出生日期

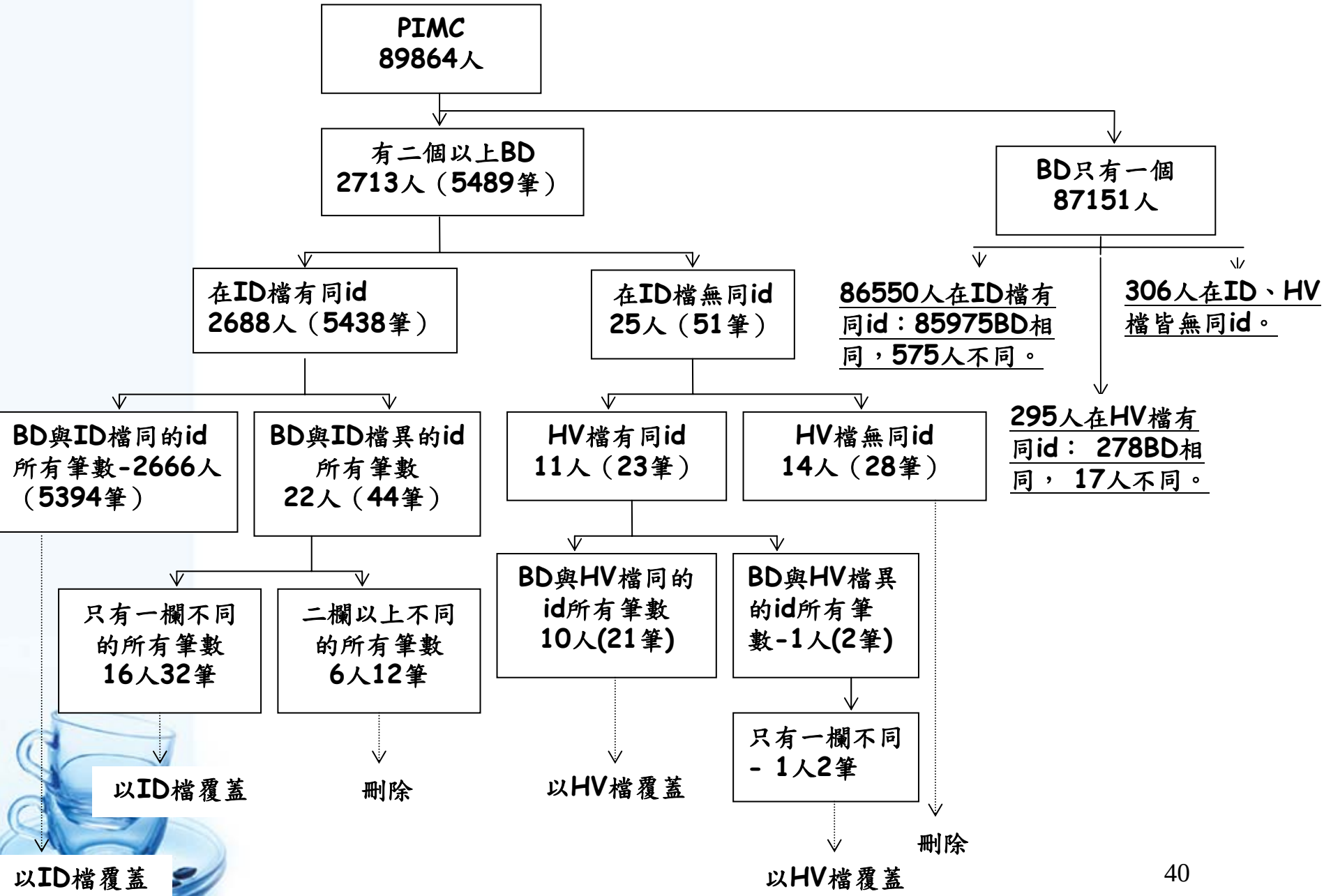
1. 檢視同一ID曾出現過之id_birthday，發現曾出現之birthday並不盡相同的ID，共有2,713個（5,489筆數），其中分為三種狀況：

同一ID有二個BD(2,652)，同一ID有三個BD(59)，同一ID有四個BD(2)

2.比對健保總ID檔 (psyid2002,即承保檔)及HV檔(合併HV及HV1997-2003)

步驟三：刪除age<5的id（共226個ID，1,438筆）

最後得到 89,618個ID，873,404筆就醫資料


PIMC
89864人
有二個以上BD
2713人（5489筆）
BD只有一個
87151人
在ID檔有同id
2688人（5438筆）
在ID檔無同id
25人（51筆）
86550人在ID檔有同id：85975BD相同，575人不同。
306人在ID、HV檔皆無同id。
BD與ID檔同的id所有筆數-2666人（5394筆）
BD與ID檔異的id所有筆數
22人（44筆）
HV檔有同id
11人（23筆）
HV檔無同id
14人（28筆）
295人在HV檔有同id： 278BD相同， 17人不同。
只有一欄不同的所有筆數
16人32筆
二欄以上不同的所有筆數
6人12筆
BD與HV檔同的id所有筆數
10人(21筆)
BD與HV檔異的id所有筆數-1人(2筆)
只有一欄不同 - 1人2筆
以ID檔覆蓋
刪除
以HV檔覆蓋
刪除
以ID檔覆蓋
以HV檔覆蓋

PIMC-總檔整理(3)

- 共刪除1486人如下：
  - 在第一步驟刪除1240人：為性別欄位空白、外國人及id欄位不完整者
  - 在第二步驟時刪除20人：為生日有二筆以上，PIMC的id_birthday與ID檔的id_birthday不同，並且在年、月、日三個欄位中，有二個欄位以上不同的筆數(套回該人所有筆數)刪除，共有6人；此外，生日二筆以上而在HV檔及ID檔中找不到該人可以對照則刪除，共有14人；因此，此部分刪除20人。
  - 在第三步驟再刪除年齡小於5歲者，共226人。

Basic features of PIMC after dataset cleaning (n=89,618)

- Gender: M 51,588 (57.56%)
  F 38,030 (42.44%)
- Mean age: 44.3 (15.04)

藥物使用分析

- 建立研究病人群
- 建立欲分析藥物列表
- 設定藥物使用定義
- 選取分析方法
- 門診檔中之相關可用欄位：藥品代號、藥品用量、藥品使用頻率、總量、含量
- 住院檔中之相關可用欄位：醫令代碼、醫令數量、含量

藥物使用之研究要進行深入分析時，碰到一大難題：

由健保申報資料庫提供之欄位資料，難以精確計算藥品使用天數與劑量

藥品使用天數計算方法一

$$\text{使用天數} = \frac{\text{藥品總數量}}{\text{使用頻率} \times \text{藥品用量}}$$

- 只能使用於門診檔
- 「藥品使用頻率」的寫法繁雜(如有BID, BID&HS, BIDHS, BID HS, BIDHS HS, BIDHS QN, CAPBID, TABBID等)
- 無法直接作運算，且逐項自行定義，不僅耗時也會有bias存在。

藥品使用天數計算方法二

$$\text{使用天數} = \frac{\text{醫令數量（總量）}}{DDD}$$

- DDD (defined daily dose), by WHO
- 限制
  - 所定義之藥品的劑量，適用於18-65歲之成年人。
  - 若病人的劑量因肝腎功能而有所調整，此方法可能會錯估藥物使用天數。
  - 台灣臨床上習慣用劑量與DDD所定義者不一定相同。

藥物副作用研究

- 病例對照法
  - 設定條件，選取病例組與對照組
  - 分析兩組的藥物暴露狀況
  - 可使用資料庫執行
- 存活分析法
  - 設定條件，選取使用欲分析藥物的病人群
  - 分析病人群於用藥期間內事件發生狀況
  - 病人的用藥期難以掌握，且常有中斷的狀況，導致事件發生的分析不易

ORIGINAL CONTRIBUTION

The Association Between Carbamazepine and Valproate and Adverse Cutaneous Drug Reactions in Patients With Bipolar Disorder

A Nested Matched Case-Control Study

Susan Shur-Fen Gau, MD, PhD,†‡ Pei-Fong Chao, MS,§ Yu-Jun Lin, MD,* Ching-Jui Chang, MD,†‖¶ and Churn-Shiouh Gau, PhD§#*

J. Clin Psychopharmacol, 2008, in press

研究限制

- 關於「事件發生」的定義，只能使用疾病代碼或相關處置作為選取條件
- 對於一些須由檢驗數據或身體狀況改變來評估的副作用，如藥物造成的肝腎功能異常或體重增加等，較難由資料庫作分析
- 另外由於未能與死亡檔串聯，難以執行相關死亡風險的分析

Others: outcome research, etc.

ORIGINAL CONTRIBUTION

A Pharmacoeconomic Analysis of Atypical Antipsychotics and Haloperidol in First-Episode Schizophrenic Patients in Taiwan

Susan Shur-Fen Gau, MD, PhD,† Ching-Hu Chung, PhD,‡ and Churn-Shiouh Gau, PhD§*

(*J Clin Psychopharmacol* 2008;28:271–278)

結語

- 雖然有研究限制，臺灣全民健保資料庫仍是臨床研究及衛生政策研究的寶庫
- 有好的研究產出，需要臨床專業、公共衛生、統計等專長學者的合作

Any Questions?